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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/144,838 08/31/98 SIANI

M GRFN-020/01U

EXAMINER

HM12/0921

WESSENDORF, T

COOLEY GODWARD
ATTENTION: PATENT GROUP
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ART UNIT

PAPER NUMBER

1618

11

DATE MAILED:

09/21/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/144,838

Applicant(s)

Siani et al

Examiner

T. Wessendorf

Group Art Unit

1618



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-51 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-51 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Other:

1) FAX TRANSMISSION

2) Raw Sequence Listing Error Summary

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1618

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Printout of Raw Sequence Listing Error Summary Report.

Election/Restriction

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Art Unit: 1618

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1- 27 drawn to cross-over protein, cross-over protein library, composition and kit, classified in classes 514 and 530, subclasses 12 and 350, respectively.
- II. Claims 28-36, drawn to method of making cross-over protein and library of cross-over proteins, classified in class 530, subclasses 333-339 .
- III. Claims 37-51 drawn to method of screening a cross-over protein library, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different processes as recited e.g., at page 10, line 21 up to

Art Unit: 1618

page 11, line 1 or as evidenced from the teachings of Canne (J. Am. Chem. Soc.).

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are independent methods having different modes of operation and practicing the method yield different products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claim 3 is generic to a plurality of disclosed patentably distinct species comprising species of ligating groups:

- A). Native chemical ligation
- B). Oxime forming chemical ligation
- C). Thioester forming ligation
- D). Thioether forming ligation
- E). Hydrazone forming ligation
- F). Thiazolidine forming ligation

Art Unit: 1618

G). Oxazolidine forming ligation

Each of these species differ in chemical structure and therefore in chemical reaction or ligation with the cross-over protein that results in different cross-over proteins or products. For example the oxime forming chemical contains a structure or the radical $\text{-CH}(\text{:N-OH})$ which differs from the structure or radical thioether of R-S-R or the hydrazone -NH-N:C and etc.

Claims 15-17, 23-25, 49-51 are generic to a plurality of disclosed patentably distinct species comprising species having different peptide sequences for the amino and/or carboxyl ends. Each of the peptide sequences e.g., Seq. ID. Nos. 11-18 differ in each primary structure as the amino acid residues present therein are different and the peptide sequences are of differing length. Therefore, the different peptide structures would have different reactivity and specificity that would result in different cross-over protein products.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Art Unit: 1618

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 3967. The examiner can normally be reached on Mon. to Fri. from 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for this Group is (703) 308-4242.

Art Unit: 1618

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Tdw

9/1/99

T. D. Winkler
Patent Examiner